UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

CIVIL ACTION NO. 09-12176-RGS

UNITED STATES OF AMERICA,
ex rel. DAVID PROVUNCHER

v.

ANGIOSCORE, INC.

MEMORANDUM AND ORDER ON
DEFENDANT'S MOTION TO DISMISS
RELATOR'S SECOND AMENDED COMPLAINT

August 3, 2012

STEARNS, D.J.

Plaintiff/relator David Provuncher is a former employee of defendant Angioscore, Inc., a biotechnology firm that manufactures and distributes angioplasty catheters under the trade name AngioSculpt. Provuncher brought this "whistle blower" action based on allegations that AngioScore "deliberately suppressed adverse event reporting of injuries and incidents" involving the AngioSculpt EX PTCA Scoring Balloon Catheter (EX Catheter), and sold it knowing that it was "defective" in violation of the federal False Claims Act (FCA), 31 U.S.C. §§ 3729 (a)(1)(A)-(B) (Counts I and II). Provuncher further alleges that as a result of his "attempt[s] to halt such conduct by persuading [Angioscore] that the EX Catheter was defective and that the company had to report adverse events to the [Food and Drug Administration (FDA)]," he was

terminated in violation of 31 U.S.C. § 3730(h) (Count III), and in violation of a Massachusetts public policy protecting at-will employees from retaliatory discharge (Count IV).

On September 15, 2011, Angioscore filed a motion to dismiss Provuncher's Amended Complaint. This court allowed the motion on May 1, 2012, finding that: Count I of the Amended Complaint failed to "allege the representative transactions with particularity"; Count II did "not connect any purportedly false statement to a specific claim that was submitted to the government"; Count III failed "to plead a causal connection between Angioscore's decision to terminate [Provuncher's] employment and its knowledge or perception that he was engaged in protected FCA-related activity"; and finally, that Provuncher's personally-held qualms over marketing the EX Catheter did not implicate the Massachusetts public policy exception in Count IV. *See* May 1, 2012 Mem. and Order[1] at 8, 9, 16, and 18. However, the court granted Provuncher leave to file a Second Amended Complaint (SAC) conforming to the pleading standard set out in *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) ("To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to state a claim to relief that is plausible on its face."), and the requirements of Fed. R. Civ. P. 9(b). *See United States ex rel. Duxbury v. Ortho Biotech Prods., L.P.*,

[1] The underlying facts of the case are set out in the May 1, 2012 Order.

579 F.3d 13, 29-30 (1st Cir. 2009).

Provuncher's SAC sets out the same four Counts, while adding some supporting detail regarding the alleged false claims presented by Angioscore to the government.[2] *See, e.g.*, SAC Tables 3 & 4 and Ex.s C & D. The basic theory of the case, however, remains unchanged. Provuncher premises the lawsuit on what he describes as the "routine separation" of the EX Catheter, which he claims renders the catheter "defective; or . . . misbranded; or . . . medically unnecessary or worthless." Under Provuncher's theory, any claim for payment for any EX Catheter manufactured prior to June of 2009 is ipso facto a "false claim" under the FCA because by his reasoning every such catheter sold was defective and therefore had no value. *See* SAC ¶¶ 4-5; Sur-Reply at 2-3. The problem with the theory is that Provuncher bases it on but 15 documented instances of separation out of the 3,750 EX Catheters that were manufactured prior to June of 2009, and sold and implanted. *See* SAC ¶ 36 (alleging 5 separations); ¶ 43 (alleging 10 additional separations); ¶ 81 (alleging more than 3,750

[2] The court agrees with Angioscore that Provuncher cannot meet the pleading requirements of Rule 9(b) by simply "multipl[ying] the number of procedures performed with such units at each identified hospital by the percentage of such procedures ordinarily paid for by Medicare for each institution." Opp'n at 11; SAC at Table Three. Similarly, the naked allegation that the 115 sales to VA Hospitals and U.S. military hospitals (listed in Table 4) that took place between June and October of 2009 gives rise to an actionable claim adds nothing absent any evidence that these units were came from the later-recalled lots. *See* SAC ¶ 91.

of the EX Catheters were implanted during angioplasty procedures); and ¶ 84 ("[Angioscore] knew that because no one could predict which units would fail, and because those that did fail could cause serious injury, none of the units were sufficiently reliable to be used in humans."). It simply does not follow that, based upon a failure rate of 0.4% of a sensitive medical device, every such device sold is defective.

Unlike the deliberate sale of batches of say, contaminated beef or nonfunctioning munition to the U.S. military, the provision of a sophisticated medical device that almost inevitably will be subject to a statistically predictable failure rate, is not the evil that Congress sought to root out by passage of the False Claims Act. *See* J. Randy Beck, The False Claims Act and the English Eradication of Qui Tam Legislation, 78 N.C. L. Rev. 539, 555 (2000). While Provuncher may be correct that any separation of the EX Catheter has "potentially catastrophic consequences for patients," the issue is one properly committed to the policing power of the FDA.[3] Provuncher admits as much. He alleges in the SAC that he reported his concerns about the safety of the EX Catheter to the FDA which then "audited Angioscore's adverse event reporting" and review[ed] the true incidence of product failure." SAC ¶¶ 68, 95. However, the FDA chose not to suspend or withdraw its consent for the device, and in fact approved the

[3] There has been no documented instance of a human fatality associated with the 15 EX Catheter separations.

PMA Supplements, thereby authorizing continued marketing of the EX Catheter. It was Angioscore that voluntarily recalled the Pre-June version of the EX Catheter in December of 2009. If anyone in fact is harmed by an implant of the EX Catheter, their recourse is to state and federal products liability laws and not to the False Claims Act. *See United States ex rel. Roop v. Hypoguard USA, Inc.*, 559 F.3d 818, 822-823 (8th Cir. 2009) (finding that "counsel['s] described additional allegations of consumer injury and non-compliance with the [FDA's Medical Device Reporting Regulations] [were] arguably relevant to a products liability case but . . . insufficient to satisfy the Rule 9(b) requirement that FCA fraud claims be pleaded with particularity.").

With regard to Provuncher's retaliation claims, the court will simply iterate the point it made earlier. It is undisputed that the decision-makers at AngioScore were unaware of the fact that Provuncher had contacted the FDA when they terminated his employment**.** As the First Circuit has recently observed, it is a commonsensical matter that there must be evidence that the alleged retaliator knew of the plaintiff's protected activity for the retaliation claim to be actionable. *See Alvarado v. Donahue*, 2012 WL 2926162, at *5 (1st Cir. July 19, 2012).

ORDER

For the foregoing reasons, defendant's motion to dismiss Provuncher's Second

Amended Complaint is ALLOWED.

SO ORDERED.

/s/ Richard G. Stearns

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UNITED STATES DISTRICT JUDGE